



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2009-0154; FRL-9955-08]**

### **Final Test Guidelines; OCSPP Series 850 Group A – Ecological Effects Test Guidelines; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is announcing the availability of final test guidelines, OCSPP Series 850 Group A – Ecological Effects, OCSPP Test Guidelines 850.1000, 850.1010, 850.1020, 850.1025, 850.1035, 850.1045, 850.1055, 850.1075, 850.1300, 850.1400, 850.1710, 850.1730, 850.1735, and 850.1740. These test guidelines are part of a series of test guidelines established by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in testing pesticides and chemical substances. The test guidelines serve as a compendium of accepted scientific methodologies and protocols that are intended to provide data to inform regulatory decisions. The test guidelines provide guidance for conducting the test, and are also used by EPA, the public, and companies that submit data to EPA.

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**SUPPLEMENTARY INFORMATION:****I. Introduction**

EPA is announcing the availability of final test guidelines, OCSPP Series 850 Group A – Ecological Effects, OCSPP Test Guideline 850.1000, 850.1010, 850.1020, 850.1025, 850.1035, 850.1045, 850.1055, 850.1075, 850.1300, 850.1400, 850.1710, 850.1730, 850.1735, and 850.1740.

These test guidelines are part of a series of test guidelines established by OCSPP for use in testing pesticides and chemical substances to develop data for submission to the Agency under the Federal Food, Drug and Cosmetic Act (FFDCA) section 408 (21 U.S.C. 346a), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*). The test guidelines serve as a compendium of accepted scientific methodologies and protocols that are intended to provide data to inform regulatory decisions under TSCA, FIFRA, and/or FFDCA.

The test guidelines provide guidance for conducting the test, and are also used by EPA, the public, and companies that are subject to data submission requirements under TSCA, FIFRA, and/or FFDCA. As guidance documents, the test guidelines are not binding on either EPA or any outside parties, and EPA may depart from the test guidelines where circumstances warrant and without prior notice. At places in this guidance, the Agency uses the word “should.” In this guidance, use of “should” with regard to an action means that the action is recommended rather than mandatory. The procedures contained in the test guidelines are recommended for generating the data that are the subject of the test guideline, but EPA recognizes that departures may be

appropriate in specific situations. You may propose alternatives to the recommendations described in the test guidelines, and the Agency will assess them for appropriateness on a case-by-case basis.

## **II. General Information**

### *A. Does this Action Apply to Me?*

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of pesticides and chemical substances for submission to EPA under TSCA, FIFRA, and/or FFDCA, the Agency has not attempted to describe all the specific entities that may be affected by this action.

### *B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket for this document.* The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2009-0154, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

2. *Electronic access to the OCSPP test guidelines.* To access OCSPP test guidelines electronically, please go to <http://www.epa.gov/test-guidelines-pesticides-and->

*toxics-substances*. You may also access the test guidelines in <http://www.regulations.gov>, grouped by series under docket ID numbers: EPA-HQ-OPPT-2009-0150 through EPA-HQ-OPPT-2009-0159 and EPA-HQ-OPPT-2009-0576.

### **III. Overview**

#### *A. What Action is EPA Taking?*

EPA is announcing the availability of final test guidelines under Series 850, Group A – Ecological Effects, entitled “Group A (850.1000 Series) - Aquatic and Sediment-Dwelling Fauna, Aquatic Microcosm and Field Testing” and identified as OCSPP Test Guidelines 850.1000, 850.1010, 850.1020, 850.1025, 850.1035, 850.1045, 850.1055, 850.1075, 850.1300, 850.1400, 850.1710, 850.1730, 850.1735, and 850.1740.

EPA’s OCSPP has established a unified library of test guidelines for use in developing data for submission to EPA under the TSCA, FFDCA, and FIFRA. Beginning in 1991, EPA initiated an effort to harmonize the test guidelines within OCSPP, as well as to harmonize the OCSPP test guidelines with those of the Organization for Economic Cooperation and Development (OECD). The process for developing and amending these test guidelines has included public participation and the extensive involvement of the scientific community, including peer review by the FIFRA Scientific Advisory Panel (SAP), the Science Advisory Board (SAB), and other expert scientific organizations. With this notice, EPA is announcing the availability of the final OCSPP Series 850 Group A -Ecological Effects Test Guidelines for use in testing chemical substances and developing data for submission to EPA. Guidelines in this series were made available for public comment by notice in the **Federal Register** (61 FR 8279, March 4, 1996), peer

reviewed on May 29, 1996 by the SAP, and subsequently revised in response to SAP and public comments.

Based on comments from the SAP and from the public, the following changes were made in the final harmonized environmental effects test guidelines:

*1. Guideline group series name change.*

EPA is changing the name of the Group A Series “Aquatic Fauna” to “Aquatic and Sediment-Dwelling Fauna, Aquatic Microcosm and Field Testing” broadening the scope of this guideline series to all test guidelines evaluating effects to aquatic fauna contained in Group A.

*2. Name change for the OCSPP 850 guidelines.*

EPA is changing the name of the 850.1735 “Whole Sediment Acute Toxicity Invertebrates, Freshwater” guideline to “Spiked Whole Sediment 10-Day Toxicity Test, Freshwater Invertebrates.” Likewise, EPA is changing the name of the 850.1740 “Whole Sediment Acute Toxicity Invertebrates, Marine” guideline to “Spiked Whole Sediment 10-Day Toxicity Test, Saltwater Invertebrates.” The new names reflect the understanding that a 10-day exposure is not necessarily reflective of an acute exposure when considering the life-cycle duration of the organisms, as well as identify the nature of the treated test media. In addition, the use of “saltwater” instead of “marine” reflects newer terminology. The 850.1075 “Fish Acute Toxicity Test, Freshwater and Marine” has changed to “Freshwater and Saltwater Fish Acute Toxicity Test” to also reflect newer terminology. Additionally, the 850.1020 “Gammarid Acute Toxicity Test” has changed to “Gammarid Amphipod Acute Toxicity Test” to better identify the test organism.

### 3. *Harmonization of guideline organization.*

The SAP recommended that the ecological effects guidelines include the same organizational format and that the tables summarizing test conditions for appropriate guidelines contain consistent concepts across guidelines. As a result of these suggestions, information was moved within the guidelines, but the information remained the same. Tables summarizing test conditions and test validity elements were added to guidelines in which species specific or laboratory measurements were defined. In all guidelines where a calculated response measure (e.g., reproductive output) was derived from direct response measures (e.g., number of offspring), equations were provided.

### 4. *Highlights of technical changes.*

#### a. *Addition of a limit test option.*

Public comments indicated that a limit test could be an option to a definitive test in additional guidelines. A limit test provides an opportunity to reduce the number of animals to be tested and/or resources. Guidelines where a limit test is appropriate and a limit test option was added include the following: 850.1010 “Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids”; 850.1020 “Gammarid Acute Toxicity Test”; 850.1025 “Oyster Acute Toxicity Test (Shell Deposition)”; 850.1035 “Mysid Acute Toxicity Test”; 850.1045 “Penaeid Acute Toxicity Test”; 850.1055 “Bivalve Acute Toxicity Test (Embryo-Larval)”; 850.1300 “Daphnid Chronic Toxicity Test”; 850.1735 “Whole Sediment Acute Toxicity Invertebrates, Freshwater”; 850.1740 “Whole Sediment Acute Toxicity Invertebrates, Marine”.

b. *Modification of limit dosage or concentration “cut-off” values.* The limit dosage or concentration values for tests for pesticides were originally set at values seen in

the literature as “cut off” values. It was believed that few, if any, pesticides would be applied at a label rate that would result in residues equal to or greater than these values. However, if there are cases where estimated environmental residue values are higher than limit values provided in the Public Drafts, or there are cases where actual or expected environmental exposure levels may be higher than the limit values for industrial chemicals, language was added. To address these case-by-case occurrences, language was added saying that the limit value should be adjusted upward if environmental exposure concentrations are expected to be higher than the limit value. In addition, the limit concentration for industrial chemicals was changed from “1,000 milligrams/Liter (mg/L)” to “100 mg/L” for acute toxicity tests and “10 mg/L” for chronic tests.

*5. Public draft guidelines that were not finalized.*

The draft 850.1790 “Chironomid Sediment Toxicity Test” and 850.1800 “Tadpole/Sediment Subchronic Toxicity Test” guidelines were not finalized as the 1996 FIFRA SAP report recommended dropping these guidelines for reasons such as another sediment guideline was available (*i.e.*, 850.1735).

The draft 850.1850 “Aquatic Food Chain Transfer”, 850.1900 “Generic Freshwater Microcosm Test, Laboratory”, 850.1925 “Site-Specific Aquatic Microcosm Test, Laboratory”, and 850.1950 “Field Testing for Aquatic Organisms” guidelines were not finalized as these types of tests are generally considered higher-tiered tests that are designed to meet specific testing needs, which may vary from study to study.

The draft 850.1500 “Fish Life Cycle Toxicity” and 850.1350 “Mysid Chronic Toxicity Test” were also not finalized. The EPA acknowledges that a test guideline for the Endocrine Disruptor Screening Program (EDSP) was developed for fish (890.2200-

Medaka Extended One Generation Reproduction Test (MEOGRT) (Ref. 1)).

Additionally, a mysid 2-generation toxicity test was developed for the EDSP but was not finalized into a test guideline (Ref. 2). As such, the Agency intends to consider and potentially incorporate, as appropriate, test design features from both the EDSP MEOGRT and the mysid 2-generation toxicity test when updating and finalizing the existing draft 850.1500 fish life cycle and 850.1350 mysid chronic life cycle test guideline.

With regard to the 850.1085 “Acute Fish Toxicity Mitigated by Humic Acid Test”, the EPA is re-evaluating how the outcomes of these types of tests represent natural processes in the environment, what chemicals are expected to be impacted by this type of process, and the extent to which these tests can be used to represent environments that vary in their level of total organic carbon.

*B. How Were The Final Test Guidelines Developed?*

In 1996, draft guidelines were made available by notice in the **Federal Register** (61 FR 8279, March 4, 1996) for public comment through the EPA docket. These guidelines were also submitted by EPA for peer review by the FIFRA Scientific Advisory Panel (SAP) on May 29, 1996 (61 FR 19276, May 1, 1996). These final guidelines incorporate changes recommended by the SAP and other changes resulting from the public comment received in response to the March 4, 1996 draft guidelines. The majority of comments and changes dealt with the organizational structure of the guideline group series, consistency of organization and format across the ecological effects guidelines, addition of tables summarizing test conditions, addition of tables summarizing test validity elements, consistency in use of terminology, and updating of references. The



reporting section of each guideline now provides a list of study specific information to include in a study report based on study reporting requirements specified in 40 CFR 160.185 for FIFRA and 40 CFR 792.185 for TSCA.

#### **IV. References**

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

1. EPA. Endocrine Disruptor Screening Program Test Guidelines 890.2200: Medaka Extended One Generation Reproduction Test (MEOGRT), July 2015. EPA No. 740-C-15-002. 2015. Docket ID No. EPA-HQ-OPPT-2014-0766-0001.
2. EPA. Guidance: Endocrine Disruptor Screening Program Test Guidelines; Three Tier 2 Non-Mammalian Tests. 2015. Docket ID No. EPA-HQ-OPPT-2014-0766-0001.

**Authority:** 7 U.S.C. 136 *et seq.*; 15 U.S.C. 2601 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: November 30, 2016.

James Jones,

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